REMARKS

Claims 1-49 were presented.

Claims 6, 23, 31 and 46 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Claims 7-10, 24-26, 32-35 and 47-49 were likewise rejected because they depend respectively from claims 6, 23, 31 and 46.

Claims 1-5 and 27-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,759,157 to Harada et al. (hereinafter "Harada") in view of U.S. Patent No. 6,524,257 to Ogura et al. (hereinafter "Ogura").

Claims 11-13, and 36-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and further in view of U.S. Patent No. 6,405,076 to Taylor et al. (hereinafter "Taylor").

Claims 14-17, 21-22, 39, 40 and 44-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and further in view of U.S. Patent No. 4,870,973 to Ueno (hereinafter "Ueno").

Claims 18-20 and 41-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and Ueno and further in view of U.S. Patent No. 4,592,365 to Georgi (hereinafter "Georgi").

Applicants have amended independent claims 1 and 27 to more particularly define the subject matter claimed.

Independent claim 1 as amended recites that the blood pressure measurement apparatus is "configured to operate according to an oscillometric method of measuring blood pressure" and comprises "a sensor coupled to said inflatable chamber, said sensor configured to measure a signal according to the oscillometric method of measuring blood pressure, said signal comprising information indicative of a blood pressure of a vertebrate;" Claim 1 as presently amended also recites "a first analysis module, said first analysis module configured to analyze said signal during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate according to the oscillometric method of measuring blood pressure." Support for a blood pressure

measurement apparatus "configured to operate according to an oscillometric method of measuring blood pressure" is found throughout the Specification as originally filed, and at least at paragraphs [0004]-[0005], and in Figs. 1A and 1B. Support for the limitation that a systolic blood pressure and a diastolic blood pressure are measured during the inflation period is found throughout the Specification as originally filed, and at least at paragraphs [00010]-[00020], and [00044], and originally filed claims 4, 12, 19, and 25. No new matter is introduced by the amendments.

Independent claim 27 as amended recites "an oscillometric method of measuring blood pressure" and comprises the steps of "measuring a signal comprising information indicative of a blood pressure of a vertebrate, said signal generated according to an oscillometric blood pressure measurement method" and "analyzing said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate." Support for the amended claim limitations is found at the same locations in the originally filed Specification and drawings as cited for the amendments to claim 1, and also in originally filed claims 29, 34, 37, and 42. No new matter is introduced by the amendments.

Applicants have amended claims 6, 23, 31 and 46 to more particularly define the subject matter claimed, as described in more detail below. No new matter is introduced by the amendments.

Applicants have canceled eight (8) dependent claims, namely claims 4, 12, 19, 25, 29, 34, 37, and 42.

Applicants have amended the dependence of claims 5, 13, 20, 26, 30, 35, 38 and 43 to depend from non-canceled claims. No new matter is introduced by the amendments.

Applicants have added eight (8) new dependent claims 50-57. No new matter is introduced by the addition of the claims by amendment.

Claims 50, 52, 54 and 56, which depend respectively from claims 6, 23, 31 and 46, all include the limitation that the representation whether the vertebrate is a neonate is based on "an operator issuing a command" which finds support at least at paragraph [00043] as

originally filed, which recites in relevant part "The operator then issues a command to initiate the measurement, such as pressing a button. ... Alternatively, the operator can issue a command indicating that the subject is or is not a neonate."

Claims 51, 53, 55 and 57, which depend respectively from claims 6, 23, 31 and 46, all include the limitation that the representation whether the vertebrate is a neonate is based on "deducing from data in a database whether said vertebrate is a neonate vertebrate." This limitation finds support at least at paragraph [00043] as originally filed, which states that "As required, initialization information can also be downloaded from a database. ... In one embodiment, at box 204, the apparatus performs an analysis of the signals that it detects to determine whether the subject vertebrate is a neonate." At paragraph [00036], there is stated "An example of a neonate vertebrate is a human having an age of 28 days or less since birth." It is conventional in medical practice that a database of information about a patient includes the birth date of a patient. It is common that computer-based apparatus used in medical practice includes a real time clock that indicates the current date, if for no other reason than to time stamp data. Accordingly, it is a simple matter to determine whether a birth date of a patient recorded in a database is or is not more than 28 days earlier than the current date, and therefrom to deduce whether the patient is a neonate.

After all amendments, claim cancellations, and additions of new claims, claims 1-3, 5-11, 13-18, 20-24, 26-28, 30-33, 35-36, 38-41, and 43-57 are pending in the application.

Discussion of amendments to claims 1 and 27

Applicants believe that the amendments to independent claims 1 and 27 distinguish the claims as a mended over the prior art. The amendments are offered as a *bona fide* effort to bring the claims into better condition for allowance.

There are two well known methods of measuring blood pressure in a non-invasive manner. One is the auscultatory (from auscultation or "a listening") method that relies on hearing sounds known as Korotkoff sounds (or "K-sounds"). The other is the oscillatory method that relies on pressure changes within a blood pressure cuff. There is no "listening" for sounds in the oscillatory method.

In the auscultatory method, it is well known that one listens for the K-sounds, commonly with the use of a stethoscope in the case of a human operator. The accuracy of the auscultatory NIBP method depends on the speed that the pressure is changing. The systolic and diastolic points are determined by the presence or absence of K-sounds. K-sounds are caused by blood flow being disrupted by the cuff and only can be heard during the beat of the person's heart. The auscultatory method relies on the interplay between cuff pressure and heart rate, so rapid increases or decreases in cuff pressure directly affect accuracy and precision of the blood pressure that one reads. For the typical patient being tested at rest, the time between heart beats and associated K-sounds is about one second. If the cuff pressure changes too fast, there results a lack of precision as to what the pressure is be when the K-sound occurs. If the cuff pressure changes more slowly, the actual blood pressure is obtained with greater accuracy and precision.

In the auscultatory method as taught by U.S. Patent No. 5,135,003 to Souma (hereinafter "Souma"), the cuff is inflated at 6 mmHg/second to find the estimate of diastolic pressure, represented by the first K-sound. However the error in the estimated diastolic pressure is too large because the rate of inflation of 6 mmHg/second is too fast. Souma teaches reducing the inflation rate to 4mmHg/second to read systolic pressure at sufficient accuracy during inflation. At 4mmHg/sec, there can be an error of up to about 4mmHg in the systolic reading. Because the diastolic pressure estimated during inflation is not sufficiently accurate, Souma teaches that one must then deflate to near the diastolic pressure at a slower rate to read the diastolic pressure accurately during the deflation period. Souma does not teach that one can "extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate" during only the inflation interval.

By comparison. the oscillometric method doesn't require such cooperation between the cuff pressure and the heart rate, or the K-sounds. In the oscillometric method, each pulse at different pressure acts to build an envelope that can be sensed. Increasing the speed of the pressure change can decrease the resolution of the envelope, but does not change the shape of the envelope, which can still be sensed. In the oscillometric method, the concern is that this lower resolution may limit the ability to sense blood pressure correctly, but does not change

the accuracy of the measured value of diastolic or systolic pressure as long as the envelope is sensed correctly.

Response to Rejection of Claims under 35 U.S.C. §112, 1st Paragraph

Claims 6, 23, 31 and 46 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Claims 7-10, 24-26, 32-35 and 47-49 were likewise rejected because they depend respectively from claims 6, 23, 31 and 46.

Applicants have amended claims 6, 23, 31 and 46 to more particularly define the subject matter claimed.

Claims 6 and 23 recited in relevant part "configured to sense whether said vertebrate is a neonate vertebrate". Claims 31 and 46 recited in relevant part "the step of sensing whether said vertebrate is a neonate vertebrate." The Office Action indicates that the specification describes two methods (an operator issuing a command, and downloading data from a database) to indicate whether a patient is a neonate. The word "represent" used as a verb has the meaning "stand for," signify," characterize," or "denote." The word "indicate" used as a verb has the meanings "signify," "denote," "reveal" and "show." Accordingly, Applicants respectfully submit that the usage "configured to represent whether said vertebrate is a neonate vertebrate," or the usage "comprising the step of representing whether said vertebrate is a neonate vertebrate" appropriately captures the described capability of having the apparatus become informed of the status of a patient or the method using information about the status of a patient, e.g., whether or not the patient is a neonate.

Claims 6 and 23 have been amended to recite in relevant part "configured to represent whether said vertebrate is a neonate vertebrate" and claims 31 and 46 have been amended to recite in relevant part "comprising the step of representing whether said vertebrate is a neonate vertebrate", with support as described above. No new matter is introduced by the amendments.

Applicants respectfully submit that the amendments to claims 6, 23, 31 and 46 overcome the rejections under 35 U.S.C. §112, first paragraph.

Response to Rejection of Claims under 35 U.S.C. §103(a)

Claims 1-5 and 27-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura.

1. The combination of Harada and Ogura is made to suggest that measurement during inflation at an inflation rate above 3 mmHg/second would be obvious to one of ordinary skill in the art.

The combination of Ogura with Harada is argued in the Office Action to be appropriate so as to suggest that the use of an inflation rate of 5 mmHg/sec while making a blood pressure measurement would be obvious to one of ordinary skill in the art.

2. Harada explicitly teaches measurement during inflation at an inflation rate of 2-3 mmHg/second.

The Office Action states at page 3 as regards Harada that "[t]he rate of inflation or deflation is not mentioned." Applicants note for the record that U.S. Patent No. 5,759,157 to Harada teaches slow inflation at a rate of 2 to 3 mmHg/sec at column 5, lines 42- 48, as shown by the image presented below:

CPU **28** repeats Step SA1. If a positive judgment is made at Step SA2, the control of CPU **28** goes to Step SA3. At Step SA3, the pressure regulating valve **14** is switched to a slow-inflation position in which the pressure regulating valve **14** permits the pressurized air to be supplied to the cuff **10** at a rate suitable for blood pressure measurements, for example, 2 to 3 mmHg/sec, as shown at point t_2 in FIG. **4**.

3. Harada explicitly teaches a preliminary inflation rate faster than 3 mmHg/second, but not for making a measurement.

Applicants also note for the record that the same paragraph, at lines 34-38, teaches that "At Step SA1, the pressure regulating valve 14 is placed in a quick-inflation position in

which the pressure regulating valve 14 permits a pressurized air to be quickly supplied to the cuff 10 by the air pump 18, as shown at point t_1 in FIG. 4." Therefore, Harada knows that inflation rates faster than 2-3 mmHg/second can be applied to inflate a blood pressure cuff. However, Harada explicitly elects to slow down the inflation rate to the specified 2-3 mmHg/second during the time he makes his measurement in an inflation interval.

Fig. 4 of Harada is also indicative that Harada knows to inflate at a rate faster than 2-3mmHg/second and elects not to measure blood pressure under the faster inflation condition.

4. Harada is far more expert than one of ordinary skill in the art.

Chikao Harada is a named inventor on at least 23 United States patents that relate to blood pressure measurement technology, including U.S. Patent Nos. 4,262,674 issued April 21, 1981, 4,356,827 issued November 2, 1982, 4,729,381 issued March 8, 1988, 4,901,733 issued February 20, 1990, 4,928,700 issued May 28, 1990, 4,928,701 issued May 29, 1990, 4,947,855 issued August 14, 1990, 4,951,679 issued August 28, 1990, 4,976,268 issued December 11, 1990, 5,101,829 issued April 7, 1992, 5,131,400 issued July 21, 1992, 5,179,956 issued January 19, 1993, 5,462,051 issued October 31, 1995, 5,560,366 issued October 1, 1996, 5,595,180 issued January 21, 1997, 5,617,868 issued April 8, 1997, 5,653,241 issued August 5, 1997, 5,660,182 issued August 26, 1997, 5,730,139 issued March 24, 1998, **5,759,157 issued June 2, 1998 (the reference cited)**, 6,068,601 issued May 30, 2000, 6,475,155 issued November 2, 2002, 6,748,262 issued June 8, 2004. His patents have issued over a time period of more than two decades, during which time he has worked in the same field. Applicants respectfully submit that Chikao Harada can hardly be viewed as merely "one of ordinary skill in the art," but rather is very experienced and is plainly well versed in the technology of blood pressure measurement. Toshihiko Ogura is a co-inventor at least U.S. Patent Nos. 5,595,180 issued January 21, 1997, 5,660,182 issued August 26, 1997, and 6,475,155 issued November 2, 2002 listed above. Colin Corporation is the common assignee of the patents cited as prior art on which Harada and Ogura are named inventors.

5. Ogura teaches a fast inflation rate which is not used for making a measurement.

Ogura teaches a measurement method that uses four similar measurement techniques, each applied to a different extremity of a human patient. Ogura at column 7, line 57, through column 8, line 17 teaches the use of fast inflation without making a blood pressure measurement during the inflation interval:

> A cuff-pressure changing means 60 controls, in a blood-pressure measuring operation, the air pump 36 and the four pressure control valves 26a, 26b, 26c, 26d, such that **the respective pressures PC_a, PC_b of the two upper-arm cuffs 20R, 20L are quickly increased up to a first prescribed target pressure value P_{CM} (e.g., about 180 mmHg) and the respective pressures PC_c) [sic] PC_d of the two ankle cuffs 18R, 18L are quickly increased up to a second prescribed target pressure value P_{CM} (e.g., about 240 mmHg)**, and then the pressures PC_a, PC_b, PC_c, PC_d are slowly decreased at a rate of about 5 mmHg/sec. (emphasis added)

6. Ogura only teaches making a measurement at 5mmHg/second during deflation, and not during inflation.

Ogura at column 7, line 57, through column 8, line 17 teaches.

> A cuff-pressure changing means 60 controls, in a blood-pressure measuring operation, the air pump 36 and the four pressure control valves 26a, 26b, 26c, 26d, such that the respective pressures PC_a, PC_b of the two upper-arm cuffs 20R, 20L are quickly increased up to a first prescribed target pressure value P_{CM} (e.g., about 180 mmHg) and the respective pressures PC_c) [sic] PC_d of the two ankle cuffs 18R, 18L are quickly increased up to a second prescribed target pressure value P_{CM} (e.g., about 240 mmHg), and **then the pressures PC_a, PC_b, PC_c, PC_d are slowly decreased at a rate of about 5 mmHg/sec.** (emphasis added)

At column 15, lines 39-46 et seq., Ogura teaches a representative blood pressure measuring methodology in more detail:

> Meanwhile, if a positive judgment is made at SA7, the control goes to SA8 to stop the air pump 36 and switch the two control valves 26a, 26b to their slow-deflation positions, so that the respective pressures PC_a, PC_b of the upper-arm cuffs 20R, 20L are slowly decreased at the prescribed rate, e.g., 5 mmHg/sec.

> Next, the control goes to SA9, i.e., a blood-pressure determining routine corresponding to the upper-arm-blood-pressure determining means 72.

At column 15, lines 60-65, Ogura teaches that after the blood pressure measurement is completed, the pressure in the cuff is decreased quickly:

> Then, at SA10 corresponding to the cuff-pressure changing means 60, the control device 38 switches the two control valves 26a, 26b to their quick-deflation positions, so that the respective pressures PC_a, PC_b of the upper-arm cuffs 20R, 20L are quickly decreased. Thus, the signal-reading routine is finished.

7. There is no basis for combining Ogura's rate of deflation with Harada's measurement during inflation as "obvious to one of ordinary skill" when both Harada and Ogura knew of higher inflation rates than 2-3 mmHg/second and neither taught or suggested their use during a measurement made in an inflation period.

Harada is well versed in the field of blood pressure measurements. He taught to make measurements during both inflation and deflation periods. Additionally, Harada plainly taught faster rates of inflation (and deflation) than 2-3 mmHg/second, but elected not to use those higher rates during the measurement of blood pressure.

Ogura teaches making blood pressure measurements at rates of about 5 mmHg/second during deflation. Ogura does not suggest making a measurement during an inflation period at all.

From what Applicants can determine, Ogura and Harada appear to have worked at the same time for the same employer, Colin Corporation, the common assignee of both U.S. Patent Nos. 5,759,157 and 6,524,257.

Ogura should have been on constructive notice of U.S. Patent No. 5,759,157 which issued in 1998, when he filed his priority Japanese filing in March 2001, and when he filed on October 21, 2001 the application that matured into U.S. Patent No. 6,524,257. Nevertheless, neither Harada nor Ogura teach or suggest the use of an inflation rate higher

than 2-3 mmHg/second during the making of a blood pressure measurement during an inflation period.

Applicants respectfully submit that in view of the fact that neither of Ogura and Harada teach or suggest making a blood pressure measurement during an inflation period in which the inflation rate is above 2-3 mmHg/second, then it would not be "obvious to one of ordinary skill in the art" or "obvious to try" making a measurement during an inflation period at a rate above 2-3 mmHg/second based on the disclosures of U.S. Patent Nos. 5,759,157 and 6,524,257. Applicants submit that even the recent holding of the Supreme Court of the United States in *KSR International Co. v. Teleflex Inc.* (No. 04-1350, April 30, 2007) does not require a different outcome.

Applicants submit that hindsight based on the present application is the only basis for proposing the combination of Harada and Ogura to suggest the use of a blood pressure measurement during an inflation period at a rate greater than 3 mmHg/second, e.g., in a regime that neither cited disclosure teaches or suggests. Hindsight is an impermissible basis for suggesting a combination.

The Office Action also makes reference to the following additional patents that teach measuring blood pressure during deflation intervals at deflation rates that exceed 3 mmHg/second: U.S. Patent No. 6,773,460 to Ogura, U.S. Patent No. 6,610,017 to Oka, U.S. Patent No. 6,222,035 to Packman et al. and U.S. Patent No. 6,165, 131 to Cuce at al. Applicants note for the record that although all of the cited patents were applied for in the United States after the issuance of Harada, none of the cited patents teaches measuring blood pressure during an inflation interval. The Oka patent is also assigned with Colin Corporation.

In particular Cuce teaches measuring blood pressure using a deflation rate of 6 mmHg/sec. Cuce at column 3, lines 5- 29 teaches the inflation and deflation rates of 6 mmHg/second.

> In the indirect measuring method using a manual sphygmomanometer, the procedure outlined herein below is to be followed exactly. With the patient in a horizontal position, the inflatable armband inflating step is commenced with the armband being suitably placed around a portion of the patient's limb to be used in the measurement. An ordinary pump is associated with the armband. The inflating step should not be carried out at an excessively fast

> rate, and should not produce too high a compressive force so as not to inflict painful sensations on the patient which would result in disturbed pressure readings. In particular, it is found that an optimum rate for this step would be a rise of about 6 mmHg/s in a mercury column suitably linked to the inflatable armband.
>
> Upon choking off the vessel involved in the measurement, the inflatable armband deflating step is commenced by releasing a manual exhaust screw. The patient is still in the horizontal position. Just like the inflating step, the deflating step should not be too rapid so as not to incur an underestimate of the systolic pressure value by stifling the first tones heard upon releasing the vase. Nor should the deflating step be too slow so as not to alter the pressure readings by inducing venous congestion. In this case, a secondary rise would occur in the diastolic pressure and the systolic pressure value would be under-estimated.

However, at column 9, lines 15-26, Cuce teaches that the measurement is made during the deflation of the blood pressure cuff:

> 2. Measuring Step. This second step, which starts when the reference point RF is reached, is aimed at determining systolic, diastolic, and heart beat frequency values. While air is being slowly exhausted from the inflatable armband through the pin of the secondary exhaust block 9, the controller block 18 operates the first processor implementing the first rule set FUZZY1. This first processor signals whether a heart beat has occurred. Upon the first beat, the controller block 18 records a first pressure value, corresponding to the systolic pressure value, while at the same time operating a timer (not shown) to have the heart beat frequency measured.

Therefore, Applicants respectfully submit that substituting any of U.S. Patent No. 6,773,460 to Ogura, U.S. Patent No. 6,610,017 to Oka, U.S. Patent No. 6,222,035 to Packman et al. and U.S. Patent No. 6,165, 131 to Cuce at al. for the cited U.S. Patent No. 6,524,257 would not in any way change the analysis presented hereinabove. The additional patent references are at best cumulative.

8. Applicants respectfully traverse the rejection of claims 1-5 and 27-30.

Applicants respectfully traverse the rejection previously given as being an improper rejection. Because neither Harada nor Ogura teach or suggest the limitation in claim 1 that recites "a first analysis module, said first analysis module configured to analyze said signal

during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate according to the oscillometric method of measuring blood pressure" nor the limitation in claim 27 that recites "analyzing said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate," even the combination of Harada and Ogura cannot teach what neither teaches or suggests individually. Accordingly, Applicants respectfully traverse the rejection of independent claim 1 and independent claim 27 based on an improper combination of Harada with Ogura, and further on the basis that, even if a combination of Harada with Ogura were permissible, such combination still fails to teach or suggest the subject matter claimed.

Accordingly, since a limitation of an independent claim is understood to be present in every claim dependent therefrom by 35 U.S.C. §112, fourth paragraph, Applicants respectfully submit that the Examiner has not presented a proper rejection for any claim that depends from claim 1 or from claim 27, if such rejection relies on Harada in view of Ogura for teaching, suggesting or otherwise making obvious a limitation in which a blood pressure measurement is performed and analysis is done "during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated." Applicant respectfully submits that all of claims 2-26, and new claims 50-53 which depend directly or indirectly from independent claim 1 and all of claims 27-49, and new claims 54-57 which depend directly or indirectly from independent claim 27 are patentable as depending from an allowable base claim, because dependent claims include every limitation of any claim from which they depend.

Claims 11-13, and 36-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and further in view of Taylor.

Applicants have presented arguments that Harada and Ogura fail to teach or suggest a limitation in which a blood pressure measurement is performed and analysis is done "during

said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated." Taylor is not cited to teach or suggest this missing element. Accordingly, Applicants respectfully submit that even if Taylor were combined with Harada and Ogura, the limitation in which a blood pressure measurement is performed and analysis is done "during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated" would still not be taught, suggested, or made obvious.

Applicants respectfully submit that claims 11-13 and 26-38 are therefore allowable over the combination of Harada, Ogura and Taylor.

Claims 14-17, 21-22, 39, 40 and 44-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and further in view of Ueno.

Applicants have presented arguments that Harada, Ogura and Taylor fail to teach or suggest a limitation in which a blood pressure measurement is performed and analysis is done "during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated." Ueno is not cited to teach or suggest this missing element. Accordingly, Applicants respectfully submit that even if Ueno were combined with Harada, Ogura and Taylor, the limitation in which a blood pressure measurement is performed and analysis is done "during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated" would still not be taught, suggested, or made obvious.

Applicants respectfully submit that claims 14-17, 21-22, 39, 40 and 44-45 are therefore allowable over the combination of Harada, Ogura, Taylor and Ueno.

Claims 18-20 and 41-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Ogura and Taylor and Ueno and further in view of Georgi.

Applicants have presented arguments that Harada, Ogura, Taylor and Ueno fail to teach or suggest a limitation in which a blood pressure measurement is performed and analysis is done "during said inflation interval of said inflatable chamber at a rate greater than

3 mmHg per second before said inflatable chamber is fully inflated." Georgi is not cited to teach or suggest this missing element. Accordingly, Applicants respectfully submit that even if Georgi were combined with Harada, Ogura, Taylor and Ueno, the limitation in which a blood pressure measurement is performed and analysis is done "during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated" would still not be taught, suggested, or made obvious.

Applicants respectfully submit that claims 18-20 and 41-43 are therefore allowable over the combination of Harada, Ogura, Taylor, Ueno and Georgi.

Comments regarding additional patents submitted herewith

Among the patents cited in the accompanying IDS are U.S. Patent No. 5,135,003 issued August 4, 1992 to Souma ("Souma"), U.S. Patent No. 5,730,139 issued March 24, 1998 to Miyazaki et al. (hereinafter "Miyazaki" and referred to hereinabove as one naming Harada as an inventor), and U.S. Patent No. 6,602,200 issued August 5, 2003 to Kubo et al. (hereinafter "Kubo").

Souma

As discussed hereinabove, Souma teaches an auscultatory blood pressure measurement method. For the reasons already given, Applicants submit that information pertinent to the auscultatory method of blood pressure measurement is not necessarily informative about the oscillometric method of blood pressure measurement. Furthermore, independent claims 1 and 27 as amended now explicitly exclude the auscultatory method. Accordingly, Applicants submit that the teachings of Souma are not relevant prior art.

Miyazaki

Miyazaki teaches at column 7, line 59, through column 8, line 3 as blood pressure measurement made during a slow inflation period:

> Meanwhile, when the pressure-increase BP measuring mode is selected, the cuff-pressure control device 56 opens only the slow-deflation

> valve 14a of the valve device 14 and drives the air pump 19, so that the cuff pressure P_C is slowly increased at a predetermined rate. Based on the variation of respective amplitudes of heartbeat-synchronous pulses of the pulse wave detected during this slow inflation of the cuff 10, the BP measuring device 52 determines BP values of the subject. After this BP measurement, the cuff-pressure control device 56 opens the quick-deflation valve 14b of the valve device 14, thereby quickly decreasing the cuff pressure P_C.

Miyazaki teaches at column 14, lines 4-44 that a fast inflation mode can be used to pressurize a blood pressure cuff to a predetermined target value P_t, after which a blood pressure measurement is performed at a slow deflation rate:

> FIG. 8 shows essential functions of the electronic control device 156 of the BP measuring apparatus 110. ... More specifically described, the pump-output-power control device 174 **quickly increases the pressure of the cuff 114 up to a predetermined target value P_t before a BP measurement, subsequently slowly decreases the cuff pressure for the BP measurement and, after the measurement, quickly decreases the cuff pressure.** ... The second-pump-output-power determining means 178 determines the second pump output power OP_2, i.e., **output power of the air pump 146 corresponding to a predetermined rate, V_{PA}, of increase of the cuff pressure** which is the most suitable for the current exchangeable cuff 114, based on the second time period T_2 and the first pump output power OP_1, according to a predetermined relationship (e.g., $OP_2 = f(T_2, OP_1)$) between second pump output power OP_2, and second time period T2 and first output power OP_1, and sets the determined second pump output power OP_2 according to which the pump-output-power control device 174 controls the output power of the air pump 146 to increase the cuff pressure from the third value P_3 up to the target value P_t. **The most suitable pressure-increase rate V_{PA} is 10 to 25 mmHg/sec, for example.** (emphasis added)

Based on an electronic search of the text of Miyazaki, it does not appear that Miyazaki provides an explicit numerical value for the slowly increasing or slowly decreasing changes in pressure. Accordingly, it would seem that one would have to take those teachings to refer to a conventional rate of increase or decrease, which has been understood by the Applicants and by the Examiner to be 2-3 mmHg/second.

Kubo

Kubo recites at column 2, lines 15-17, that "One object of the invention is to provide an electronic blood pressure meter capable of taking measurements as fast as possible without deteriorating precision."

Kubo teaches the use of a fast inflation rate to determine the parameters needed for a measurement made upon slow deflation of a blood pressure cuff. Kubo recites at column 3, lines 39-40, "FIG. 8 is a flowchart illustrating an entire operation of the electronic blood pressure meter of the embodiment." Kubo teaches at column 8, lines 1-58, the steps in the flowchart shown in FIG. 8. Relevant portions of that teaching include:

> With power switch 11a turned on, measurement start switch 11b is made on to start a measurement operation. Pressure pump 4 is made on to start inflating cuff 2 (step ST1). After this, with increase of the cuff pressure, the cuff pressure and pulse wave superimposed on the cuff pressure are extracted. Pulse wave feature amount calculating unit 8 obtains pulse wave amplitude data that are some feature amounts of the pulse wave. The cuff pressure and these pulse wave amplitude data in the inflation process **are used to estimate approximate systolic and diastolic pressures** by blood pressure calculating unit 7 (step ST2), and the number of pulse waves is also measured (step ST3). Here, systolic and diastolic pressures are used as examples of feature amounts.
>
> **According to the estimated and measured data, deflation rate determining unit 9 calculates deflation rate def-v by means of formula (1) shown above (step ST4). ...**
>
> The deflation rate and the upper limit inflation value are thus calculated in the inflation process, and then inflation is continued until the cuff pressure reaches the upper limit (step ST6). ... When the cuff pressure attains the upper limit (step ST6), pressure pump 4 is made off to stop inflation (ST7), ... , and accordingly deflation is started (step ST11). Once the deflation process starts, deflation control unit 14 adjusts the deflation to set the deflation rate at the one which has already been calculated in the inflation process.
>
> Deflation is started and then the cuff pressure is detected, pulse wave is extracted and pulse wave amplitude data is extracted as shown in FIG. 3. **When a required number of pulse wave amplitude data is gathered, a well-known algorithm is used to determine mean blood pressure, systolic pressure and diastolic pressure and thus blood pressure is determined (measured) (step ST12). ...**

> Measurement of blood pressure is thus completed (step ST13), the measured systolic pressure, diastolic pressure, the number of pulse waves and the like are indicated on display unit 18 (step ST14), solenoid valve 5 is opened to speedily discharge air (step ST15), and thus the operation reaches an end. (emphasis added)

Kubo only obtains values for blood pressure after measurements are made under controlled rates of deflation of the blood pressure cuff. At column 8, line 62, through column 9, line12, Kubo teaches various deflation rates in the range of 3.19 mmHg/second to 11 mmHg/second, for measurements of blood pressure that are made in different situations.

Kubo does not teach measuring blood pressure during an inflation period, but rather uses measurements during inflation to "estimate approximate systolic and diastolic pressures by blood pressure calculating unit 7." Therefore, while Kubo teaches that blood pressure measurements can be made at various rates of deflation, and also teaches that estimates of approximate blood pressure can be determined during inflation, Kubo does not teach or suggest "a first analysis module, said first analysis module configured to analyze said signal during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate according to the oscillometric method of measuring blood pressure."

If Kubo knew of, or if Kubo had considered the possibility of, making a blood pressure measurement directly during an inflation of a blood pressure cuff, which would achieve the stated object "to provide an electronic blood pressure meter capable of taking measurements as fast as possible without deteriorating precision," one would expect that Kubo would so teach (and would claim such an invention), rather than using the information obtained during the inflation period only to obtain operating parameters for the deflation interval, and then taking the added time to make a measurement upon deflation, perhaps in less time than under the normal slow deflation method.

Applicants respectfully suggest that neither Miyazaki nor Kubo teach or suggest the limitation of "a first analysis module, said first analysis module configured to analyze said

signal during said inflation interval of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal a systolic blood pressure and a diastolic blood pressure of said vertebrate according to the oscillometric method of measuring blood pressure," and accordingly, a combination of Harada with either or both Miyazaki or Kubo would still lack the necessary teaching, suggestion, or motivation to make such a limitation obvious.

CONCLUSION

Applicants respectfully request that the application be reconsidered and that the rejections of pending claims 1-3, 5-11, 13-18, 20-24, 26-28, 30-33, 35-36, 38-41, and 43-49 be withdrawn. Applicants submit that claims 1-3, 5-11, 13-18, 20-24, 26-28, 30-33, 35-36, 38-41, and 43-57 are now in proper condition for allowance, and request the issuance of a Notice of Allowance at the Examiner's earliest convenience.

If the Examiner believes that communication with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is requested to call Applicants' attorney at the phone number noted below.

Respectfully submitted,
HISCOCK & BARCLAY, LLP

By: 

Joseph B. Milstein, Ph. D., Reg. No. 42,897
200 Friberg Parkway, Suite 3001
Westborough, MA 01581
Telephone: (508) 475-6620
Facsimile: (508) 475-6660

Date: July 18, 2007

Customer No.: *44331*
44331
PATENT TRADEMARK OFFICE